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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,816	09/30/2003	Johann J. Neisz	AMS-029B	6669
EXAMINER				
GILBERT, SAMUEL G				
ART UNIT			PAPER NUMBER	
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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/675,816

Applicant(s)

NEISZ ET AL.

Examiner

Samuel G Gilbert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 15-35, 40 and 41 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-9, 11-14, 36, 38, 39 and 42 is/are rejected.
- 7) ☒ Claim(s) 5 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/1/2004.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the embodiment of claims 1-14, 36-39 and 42, a kit and method including two needles, two handles and a sling in the reply filed on 7/28/2004 is acknowledged. The traversal is on the ground(s) that the office has not established that searching the entire application would impose a serious burden MPEP §803. This is not found persuasive because in the minimum searching the embodiment of claims 24-27 would require searching connectors in class 24 and other places which is not required for the embodiment of the elected claims.

The requirement is still deemed proper and is therefore made FINAL. The text of the restriction can be found in a prior Office action.

Information Disclosure Statement

The information disclosure statement filed 6/01/2004 has been considered. Several references have not been considered (lined through); some have no publication date others are not in English and include no concise explanation of relevance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 - in line 8, "the first type of needle is different than the second type of needle" is indefinite because first and second needles have not been set forth making it unclear as to what limitation the applicant is setting forth.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6-9, 12, 13, 36, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Sohn et al (WO 97/47246).

Claims 1 and 2 - Sohn et al teaches an implantable material, sling material page 8 line 26; a first type of needle element -140- a straight needle; and a second type of needle, element -132- curved needle.

Claim 6 - the examiner is taking the insertion guns as handles, Sohn et al sets forth at least three different types of guns -30-, -41- and -90-.

Claims 7-9 - needle -140- can be a suture passer -150- including an eye -158- and a sheath -154-.

Claim 12 - the examiner is taking the insertion guns as handles, Sohn et al sets forth at least three different types of guns -30-, -41- and -90-.

Claim 13 - the curved needle -132- is longer than straight needle -140-.

Claim 36 - the use of the apparatus set forth by Sohn et al would inherently use the method as claimed.

Claim 42 - Sohn et al teaches an implantable material, sling material page 8 line 26; a first type of needle element -140- a straight needle; a second type of needle, element -132- curved needle and the examiner is taking insertion guns as handles, Sohn et al sets forth at least three different types of guns -30-, -41- and -90-.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sohn et al. (WO 97/47246) in view of Berger (2002/0091373). Sohn teaches a kit as claimed but does not teach a sheath a sheath associated with the sling. Berger teaches a sling -64- that includes a sheath -66-. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a sheath as taught by Berger with the sling of Sohn to prevent the sling of Sohn from prematurely adhering to

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the tissue while being implanted as taught by Berger, paragraph [0038]. The sutures of Sohn prove an adapter for associating the sling and the surgical needle.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sohn (WO 97/47246) in view of Cook(cited by the applicant). Sohn teaches the use of two needles one curved and one being straight. The shape of the needles are determined by the intended use, (the desired path of the needles to properly locate the suture anchor point from the needle insertion point. The selection of any particular shape for the needles used would allow the medical practitioner to use any desired needle path to delivery the sutures. EPO 0,470,308 Lemay teaches the use of shapeable needles to provide the medical practitioner the most flexible range of needle paths. Cook page 9 teaches Stamey needles having a straight configuration a 15 degrees angle and a 30 degree angle configuration. It is the examiner's position that the selection of any particular angled configuration would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the practitioner to use a variety of different needle paths to properly insert the anchor suture of Sohn.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sohn (WO 97/47246) in view of Allosling Fascia, 1999.

Sohn teaches a device as claimed including a needle(suture passer as described above) but does not teach a bladder perforation detector. Allosling teaches a suture passer for incontinence surgery including a leak detection sheath for detecting if the

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bladder has been perforated. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the detection means as taught by Allosling with the suture passer taught by Sohn to provide the advantage of having a suture passer that will allow the user to determine if the bladder has been perforated without withdrawing the suture passer and inserting a separate detection device.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 38 and 39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 62 of copending Application No. 10/005,837. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious changes in the scope of the claims

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

Claims 5 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 37 is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on M-F 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Samuel G Gilbert
Primary Examiner
Art Unit 3736

sgg